THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

JANELLE ELIZABETH BARNES, Plaintiff, v. ORTHOFIX INTERNATIONAL NV, Defendant.	CASE NO. C11-402 JCC ORDER

This matter comes before the Court on Plaintiff's motion to amend (Dkt. No. 46). The Court also considers Defendant's motion to strike (Dkt. No. 54), Defendant's motion to exclude (Dkt. No. 56), and Defendant's motion to exclude consolidated with the motion for summary judgment (Dkt. No. 59). Having thoroughly considered the parties' briefing and the relevant record, the Court finds oral argument unnecessary and hereby rules as follows.

I. BACKGROUND

This is a product liability case involving the Pain Care Pump 3000, a device that infuses anesthetic into a patient's shoulder after surgery. The device is manufactured by BREG Corporation, a division of Orthofix International NV. On December 12, 2006, orthopedic surgeon Dr. Ronald Wobig performed shoulder surgery on Plaintiff Janelle Barnes in Corvallis, Oregon. During the surgery, a catheter for the pain pump was inserted and a mixture of Marcaine and epinephrine was injected through the catheter. The pain pump remained in place and a

mixture of the same anesthetic was infused under pressure over the next 50 hours.

Plaintiff left Oregon and moved to Utah in 2007 and then to Washington in 2008. Over time, Plaintiff began to experience worsening pain. On November 24, 2008, Dr. Richard Kirby examined Plaintiff's shoulder in Seattle and diagnosed her with post-arthroscopic glenohumeral chondrolysis ("PAGCL"), a condition involving permanent loss of cartilage in the shoulder joint. Plaintiff alleges that the pain pump created an unreasonable risk of chondrolysis when used in the type of surgery Dr. Wobig performed.

The exact manner in which the pump was inserted is disputed by the parties. To understand the dispute, a brief overview of shoulder anatomy is necessary. The area outside the shoulder joint and under the acromion is called the subacromial space. The area inside the joint is called the intraarticular space. There is medical literature suggesting that a pain pump catheter inserted into the intraarticular space, the area inside the joint, can cause chondrolysis. Defendant alleges that there is no peer-reviewed medical literature establishing that subacromial placement causes chondrolysis. Dr. Wobig has testified that he inserted the pump catheter into the subacromial space of Ms. Barnes' shoulder. But much of Ms. Barnes' case is built on the theory that anesthetic from the pain pump ended up in the intraarticular space. Although the precise mechanism by which this may have happened is unknown, Plaintiff offers two main theories: the "misplacement" theory, that Dr. Wobig accidentally placed the catheter in the intraarticular space, and the "leakage" theory, that anesthetic leaked from the subacromial space to the intraarticular space.

Plaintiff now seeks to amend her complaint to add a claim for punitive damages under Oregon law. Also, Defendant seeks to exclude much of the testimony on which Plaintiff is basing her theories of causation.

II. MOTION TO AMEND

Pursuant to FRCP 15(a), a plaintiff may amend her complaint only with the opposing party's written consent or the court's leave. Rule 15(a) is very liberal and leave to amend "shall

be freely given when justice so requires." *AmerisourceBergen Corp. v. Dialysist West, Inc.*, 465 F.3d 946, 951 (9th Cir. 2006). But a district court need not grant leave to amend where the amendment: (1) prejudices the opposing party; (2) is sought in bad faith; (3) produces an undue delay in litigation; or (4) is futile. *Id.*

A. Prejudice

Defendant argues that it would be prejudiced by the amendment because it would have conducted depositions and other trial preparations differently if it had known the complaint would be amended. Defendant cites to *Morongo Band of Mission Indians v. Rose*, 893 F.2d 1074 (9th Cir. 1990), in which the Ninth Circuit affirmed the district court's denial of an amendment where the amendment would have greatly altered the nature of the litigation. The *Morongo* court did not hold that the altered nature of the litigation was fatal to amendment, merely that it entered into the balance. *Id.* at 1079. Defendant fails to show that the balance tips in its favor. In *Morongo*, after the dismissal of a complaint relating to enforcement of a tribal ordinance on non-tribal members, the plaintiffs sought to amend the complaint to add RICO and civil rights claims—a dramatic shift. Here, Plaintiff seeks only to add a damage claim, but leaves the remaining claims unchanged. Defendant has failed to show that a minor amendment of this nature would amount to prejudice.

B. Choice of Law

Washington law is presumptively the law of this case unless there is a conflict with the laws and interests of another state. *Rice v. Dow Chem. Co.*, 875 P.2d 1213, 1216 (Wash. 1994). With respect to punitive damages, the law of Washington, which does not allow them, is in conflict with the law of Oregon, which does. To determine the proper law to apply, Washington uses the "most significant relationship" test as set out in the Restatement (Second) of Conflict of Laws § 145 (1971). *Johnson v. Spider Staging Corp.*, 555 P.2d 997 (1976). Section 145 provides that when evaluating those relationships, contacts to be taken into account include: (a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the

domicil, residence, nationality, place of incorporation and place of business of the parties; and (d) the place where the relationship, if any, between the parties is centered.

Plaintiff argues that Oregon has the most significant relationship because that is where the operation was performed and where Plaintiff suffered the injury. Plaintiff cites to *Rice v. Dow Chem. Co.* for comparison. In that case, a forest service employee was exposed to significant doses of herbicides while living in Oregon and later moved to Washington where he developed leukemia. The court found:

> The relationship between the parties occurred in Oregon, the damaging product was placed in the stream of commerce and sent to Oregon, at the time of the injurious contact Plaintiff lived in Oregon, and Plaintiff was exposed to the chemicals at work while employed in Oregon. Virtually the only connection with Washington is that the disease allegedly caused by the chemicals manifested itself in this state.

Rice, 875 P.2d at 1218.

Defendant counters that because Plaintiff did not experience pain until well after her surgery, the state with the most significant relationship would be either Utah or Washington, depending on where she was residing when the PACGL developed. Alternatively, Plaintiff argues, California, the state in which the corporate conduct that allegedly resulted in insufficient warnings occurred, may have the most significant relationship.

Although there is some basis for applying California's punitive damages law, and Plaintiff indicates that she does not object, Oregon is the state with the most significant relationship. All but one of the reasons mentioned by the court in *Rice* applies in this case. The relationship between Plaintiff and Defendant occurred in Oregon, the pain pump was sent to Oregon, and at the time of the surgery Plaintiff lived in Oregon. The only difference is that Plaintiff has not alleged that she was employed in Oregon at the time of the surgery, a negligible distinction. The *Rice* court specifically held that these factors outweighed the fact that the "Defendant's main headquarters, state of incorporation, place where the product was designed or

tested, place where appropriate warnings for the label were determined or place where the product was labeled" was not in Oregon. *Id.*

Defendant also argues that in a case involving punitive damages, § 145 comment c states that if the purpose of the tort rule is to punish misconduct, the state where the conduct took place may be that of the most significant relationship. However, comment c goes on to say that if the tort rule is designed to compensate victims, then the state where the injury occurred may have the greater interest in the matter. Defendant does not argue which of these two categories California's law of punitive damages falls in to, so the argument is unilluminating.

In the event of a conflict with Washington law, Oregon substantive law governs this case. Plaintiff's motion to amend is GRANTED.

III. MOTION TO STRIKE SUPPLEMENTAL WITNESS DISCLOSURES

On December 19, 2011, the Court entered a stipulation by the parties, stating that the deadline for Plaintiff's expert disclosures would be February 10, 2012. (Dkt. No. 32). Pursuant to an agreement between the parties, Defendant disclosed its experts on March 19, 2012. Plaintiff designated Dr. Gofeld as a rebuttal witness twenty-one days later. Plaintiff also alleges that because it was apparent from Defendant's expert reports that the experts "misapprehend[ed] Plaintiff's post-operative course," she supplemented her disclosure with an additional witness, Matt Swartz, to clarify the misapprehension. Defendant moves to strike both disclosures as untimely.

A. Dr. Gofeld

FRCP 26(a)(2)(D)(ii) permits a party to disclose an expert witness within 30 days of the other party's disclosure if the evidence is "intended solely to contradict or rebut evidence on the same subject matter identified by another party." "Rebuttal evidence is admissible only where the need for it could not have been foreseen at the time the plaintiff presented its case-in-chief." *Daly v. Far Eastern Shipping Co. PLC*, 238 F. Supp. 2d 1231, 1238 (W.D. Wash. 2003) (citing *Faigin v. Kelly*, 184 F.3d 67, 85 (1st Cir. 1999)). Plaintiff summarizes Dr. Gofeld's testimony in

three points: (1) subacromial catheter placement would not provide plain relief for joint surgery; (2) blind catheter placement might penetrate the rotator cuff or joint space; and (3) anesthetic infused outside the joint can migrate into the joint. (Dkt. No. 63 at 2). While the Court is concerned that some of these points may be duplicative of Plaintiff's case-in-chief, particularly the testimony of Dr. Hasan and Dr. Kirby (Dkt. Nos. 55-5 and 55-6), it is unwilling to grant a pretrial exclusion of Dr. Gofeld's testimony in the abstract. The Court will hear the testimony of Dr. Hasan and Dr. Kirby and then decide whether Dr. Gofeld will be permitted to testify and on what subjects. Defendant's motion to strike the disclosure of Dr. Gofeld is DENIED.

B. Matt Swartz

Defendant's primary argument for the exclusion of Matt Swartz is that his testimony is not credible. Plaintiff states that Defendant's experts assume that she did not have a "honeymoon period" of improved range of motion following the surgery, an indication that she might not be suffering from chondrolysis. The purpose of Matt Swartz's testimony, Plaintiff explains, is to contradict those assumptions and testify about her range of motion during the period following the surgery. Defendant argues that this explanation would contradict Plaintiff's own expert, Dr. Hasan, who noted in his report that Plaintiff did not have the classic honeymoon period. (Dkt. No. 70-3 at 4). Issues of credibility and inconsistency are best resolved in trial. Defendant's motion to strike the disclosure of Matt Swartz is DENIED.

IV. MOTION TO EXCLUDE THE TESTIMONY OF DR. PARISIAN

Defendant moves under Fed. R. Evid. 401, 403, and 702 to exclude the testimony of Plaintiff's expert Suzanne Parisian, M.D. Federal Rule of Evidence 702 provides that if expert testimony will "assist the trier of fact to understand the evidence or to determine a fact in issue," such testimony is admissible so long as "(1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the case." Fed. R. Evid. 702. This Court must perform a gatekeeping function to ensure that the expert's proferred testimony is not only relevant but

reliable. *United States v. Freeman*, 498 F.3d 893, 901 (9th Cir. 2007) (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589, (1993)).

Plaintiff seeks to call Dr. Parisian, a former Chief Medical Officer in the FDA's Office of Device Evaluation, to testify on the FDA Section 510(k) application process, the FDA clearances that were obtained regarding pain pumps, and whether Breg's marketing, instructions, warnings and testing were appropriate given the clearance it did obtain. Defendant argues that the question of FDA clearances is a "sideshow" with no bearing on the issue of whether or not Defendant should have known and warned about a risk of chondrolysis. These issues are not as distinct as Defendant would have it. Appropriate distribution and marketing of a medical device, and the accompanying warnings, can hardly be divorced from the regulatory approval of that device. And the current state of FDA regulatory approval is such that a layman may have significant difficulty understanding the rules and obligations it imposes. Dr. Parisian has the qualifications and experience to provide the jury with informative and reliable testimony on this subject. Dr. Parisian will not, of course, be permitted to instruct the jury on the law or the ultimate issue in this matter. The Court is fully capable of ensuring that Dr. Parisian does not stray beyond the permissible bounds of expert testimony. Defendant's motion to exclude is DENIED.

V. DEFENDANT'S MOTION TO EXCLUDE CAUSATION OPINIONS

Again, Defendant seeks to limit in every way possible the information to be presented to the jury. This time, Defendant seeks to exclude the testimony of Drs. Richard Kirby and Samer Hasan (the "Causation Experts") on the grounds that their causation theories, misplacement and leakage, are unreliable. Neither theory, Defendant argues, is based on a reasonable degree of medical certainty or on objective medical literature. Instead, they are based on speculation and amount to conclusory *ipse dixit*. Defendant cites to *United States v. Redlightning*, 624 F.3d 1090, 1110 (9th Cir. 2010), arguing that where facts in the record do not support an expert's theory, exclusion is proper. In *Redlightning*, the expert's testimony about the theory of false confessions was excluded when the expert testified that he had not interviewed the defendant and that there

was no evidence at all that a false confession had been given; ultimately, he concluded that there was no reason to believe that his theory applied to the facts of the case. The present case is distinct.

Rather than presenting theories with tenuous relationships to the facts of the case, the Causation Experts' theories are a direct result of their observations in this case. To begin, the two doctors have a combined total of more than 40 years of medical experience, and can boast of distinguished resumes in the field of orthopedics. Dr. Kirby has been board-certified in orthopedics since 1984, and has focused almost exclusively on treatment of the shoulder for many years. He has been treating Plaintiff since January 2009. Dr. Hasan is a member of the American Shoulder & Elbow Surgeons, which is by nomination only and based on sustained academic and research contributions to the field. He met with Plaintiff for an independent medical examination on January 26, 2012. Both doctors performed a differential diagnosis, the standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.[1] The Ninth Circuit has long recognized that a reliable differential diagnosis passes muster under *Daubert. Clausen v. M/V New Carissa*, 339 F.3d 1049, 1058 (9th Cir. 2003). The result of the differential diagnoses was that both doctors independently ruled out all possible causes of chondrolysis *except* the infusion of anesthetic through the pain pump from December 12–14, 2006. (Dkt. Nos. 74 at ¶ 8 & 75 at ¶ 21).

The testimony of the Causation Experts is based on valid methodology and that methodology was properly applied to the facts in this case. Defendant's remaining concerns

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[1] Defendant objects that the Causation experts erred in deeming the leakage and misplacement theories "likely causes" and that these theories lack the appropriate support in the medical literature to be included in the differential diagnosis calculus. . But proper documentary support is not a prerequisite for an admissible differential diagnosis. The Supreme Court has stated that "publication . . . is not the sine qua non of admissibility; it does not necessarily correlate with reliability, and in some instances well-grounded but innovative theories will not have been published. Some propositions . . . are too particular, too new, or of too limited interest to be published." *Clausen*, 339 F.3d 1060 (quoting *Daubert*, 509 U.S. at 593).

pertain to the credibility and accuracy of the testimony, and as the Court has stated, these issues are best resolved by the jury. Defendant's motion to exclude is DENIED.

Finally, because the Court holds that Oregon substantive law applies to this case, Defendant's motion for summary judgment on Plaintiff's design-defect claim is DENIED.

VI. CONCLUSION

For the foregoing reasons, Plaintiff's motion to amend is GRANTED. (Dkt. No. 46). Defendant's motions to strike and exclude and motion for summary judgment are DENIED. (Dkt. Nos. 54, 56 & 59). Plaintiff's motion to seal is GRANTED. (Dkt. No. 71).

DATED this 23rd day of May 2012.

John C. Coughenour
UNITED STATES DISTRICT JUDGE